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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

June 22, 1998

Warning Letter
CHI-27-98

Mr. John Lee, President
Acoma Medical Imaging, Inc.
150 Chaddick Drive
Wheeling, IL 60090

Dear Mr. Lee:

During an inspection of your firm from May 12 to 15, 1998, Investigator Norman Brown determined that your firm is a manufacturer of x-ray systems and accessories. X-ray systems are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices, are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to perform quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

2. Failure to ensure that test equipment is capable of producing valid results. For example, our inspection found that the [redacted] in use on May 12, 1998, was last calibrated on June 21, 1996. At the time of the last inspection, the oscilloscope was due for recalibration on June 4, 1997.

3. Failure to control the process for the manufacture of devices. Device history records for Futurus 2001 Series found that at least three different versions of the engineering change notice were referenced for the manufacture of serial numbers 2759, 2767, and 2768.

This letter is not intended as an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge receipt of Mr. Lambrecht's response to our Form FDA 483, dated May 20, 1998. We find the response adequately addresses our concerns. However, we require verification of correction either by FDA inspection or by a third party auditor's written verification.

Until FDA has documentation to establish that such corrections have been made, Federal Agencies will be advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to prevent the repeat of these deviations. Failure to prevent these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing whether you will contract a third party audit or whether you would prefer FDA to perform a reinspection.

Your response should be sent to Stephen D. Eich, Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Hiroshi Shiiba/CEO
Acoma X-ray Industry Co., Ltd.
3-22-8 Hongo, Bunkyo-Ku
Tokyo, Japan